



Wyeth Pharmaceuticals
206 N Biddle Street
Marietta, PA 17547

Dennis J. Foley, Ph.D.
Assistant Vice President
Worldwide Regulatory Affairs

August 19, 2003

Mr. John Becher
Centers for Disease Control/Drug Service, D-09
1600 Clifton Road
Atlanta, GA 30333

**Re: STN 101106/5039 – Smallpox Vaccine Dryvax®
Extension of Dating**

Dear Mr. Becher:

Please note that Wyeth received approval on August 18, 2003 for BLA supplement 101106/5039 to extend dating from 9 to 12 months for the following lots of Smallpox Vaccine Dryvax® kits:

<u>Lot Number</u>	<u>New Expiration Date</u>
4020077	November 2003
4020076	November 2003
4030020	December 2003

Additional testing in accordance with the protocol filed to our license is planned and a CBE supplement will be filed to extend the expiration dating beyond 12 months, if appropriate.

Please note that the storage period of the vaccine after reconstitution with diluent continues to be 90 days.

Sincerely yours,

Dennis J. Foley, Ph.D.

DJF:jm

cc: J. Grabenstein (DOD)
D. Staten (CBER)
D. Yeskey (CDC)